

No. 24-1773

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

REAL TIME MEDICAL SYSTEMS, INC.,

Plaintiff-Appellee,

v.

POINTCLICKCARE TECHNOLOGIES, INC. D/B/A POINTCLICKCARE,

Defendant-Appellant.

On Appeal from the United States District Court for the
District of Maryland at Greenbelt

BRIEF FOR *AMICI CURIAE* AMERICAN HOSPITAL
ASSOCIATION AND ELECTRONIC HEALTH RECORD
ASSOCIATION IN SUPPORT OF PETITION FOR
REHEARING AND REHEARING EN BANC

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- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by all parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
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Pursuant to FRAP 26.1 and Local Rule 26.1, the American Hospital Association and the Electronic Health Record Association, who are *amici curiae*, make the following disclosure:

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☐ YES ☒ NO
2. Does party/amicus have any parent corporations?

☐ YES ☒ NO

If yes, identify all parent corporations, including all generations of parent corporations: Neither *amici curiae* has a parent corporation. The Electronic Health Record Association is a professional community within the Healthcare Information and Management Systems Society, a non-profit organization that has no parent corporation.

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity?

____YES [X] NO

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation?

____YES [X] NO

If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question)

____YES ____ NO

If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding?

____YES [X] NO

If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim?

____YES [X] NO

If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: s/ James E. Tysse

Date: April 2, 2025

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STATEMENT OF INTEREST OF AMICI CURIAE¹

The Electronic Health Record Association (“EHR Association”) and American Hospital Association (“AHA”) submit this brief as *amici curiae* in support of Appellant-Petitioner PointClickCare Technologies, Inc.

The American Hospital Association (“AHA”) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are addressed in national health policy development, legislative and regulatory debates, and judicial matters. Its member hospitals regularly receive requests for patient data from a range of requestors, including healthcare providers, health information exchanges and networks, and patients.

The EHR Association is an advocacy group within the Healthcare Information and Management Systems Society. It represents 29 companies that develop and supply electronic health record (“EHR”) software used by over 80% of physicians’ practices and hospitals

¹ Under FRAP 29(a)(4)(E), no party’s counsel has authored this brief in whole or in part, and no party, party’s counsel, or person (other than *amici curiae*, their members, and their counsel) made any monetary contribution to fund this brief.

nationwide. The EHR Association believes that the adoption of EHR is essential to improve the quality of patient care as well as the productivity and sustainability of the healthcare system.

For years, *amici* have worked with their members and the Department of Health and Human Services (“HHS”) on data-exchange standards and the issue of “information blocking.” *Amici* have assisted members in developing policies to ensure they are responding to health information requests in a timely, consistent, and reasonable manner. The panel’s opinion invents new requirements found nowhere in the Cures Act or the relevant regulation. *Amici* submit this brief to explain why the opinion is both wrong and destined to have crippling effects for EHR developers and hospitals nationwide.

INTRODUCTION AND SUMMARY OF ARGUMENT

Although PointClickCare raises several issues, *amici* submit this brief to explain why its first issue—the panel’s serious misreading of the “Manner Exception”—will have destructive consequences for health providers (like hospitals), health IT vendors, and other regulated actors. Indeed, the risk of such faulty and inconsistent regulatory interpretations by state and federal judges is exactly why Congress made HHS the sole enforcer of this comprehensive and technical administrative scheme—and why *amici* earlier argued that private parties should not be permitted to circumvent Congress’s choice to bar private enforcement. *See* Am. Br. 7-11 (Sept. 23, 2024), ECF No. 26.²

HHS’s “Manner Exception” is critical to the operation of Congress’s information-blocking ban. It is designed to encourage market-based information-sharing solutions, while providing actors flexibility in

² Given the preliminary-injunction posture of this case, and the panel’s conclusion that the preemption arguments were “forfeited” (and, accordingly, unnecessary to the holding), Op. 29-30, *amici* respectfully submit that, if the Court does not grant rehearing, the panel should revise its opinion to omit that discussion. That would ensure that future litigants in this circuit are not precluded from raising those arguments in a case in which they are “preserve[d],” adequately briefed by the parties, and fully addressed at argument. *Id.*

offering standards-based access to health information. Rather than force actors to share information in whatever manner requested, the Exception offers an alternative: An actor may use one of the standardized manners outlined in the information-blocking regulations whenever the parties “cannot reach agreeable terms” over the specific manner requested—including when the actors simply “do not want to” share information in the manner requested.

No part of the Manner Exception requires actors to “negotiate” or make “good-faith efforts” to reach agreeable terms for every individual request they receive; quite the opposite. Yet that is what the panel effectively rewrites the Exception to say. In its view, an actor can offer standards-based solutions only if the parties reach an “impasse” after using “reasonable efforts” to reach a negotiated agreement.

Those judicially invented requirements are both wrong and deeply consequential. They will force actors to negotiate over all requests for electronic health information—including requests that are objectively unreasonable—backed by the threat of open-ended litigation in which the actors bear the burden of proof. That will inevitably result in higher costs ultimately borne by the healthcare system, patients, and taxpayers.

Because the panel was mistaken on this issue of first impression—and because that mistake will have disastrous consequences nationwide—this Court should grant PointClickCare’s petition for rehearing.

ARGUMENT

I. THE PANEL’S INTERPRETATION OF THE MANNER EXCEPTION IMPOSES AN OPEN-ENDED NEGOTIATION REQUIREMENT IN VIOLATION OF CONGRESS’S AND HHS’S CLEAR DIRECTION

A. The Manner Exception Is Designed To Give Actors Flexibility And Clarity In Fulfilling Requests For Electronic Health Information

Congress passed the Cures Act to allow greater sharing of electronic health information and generally to prohibit “information blocking”—*i.e.*, practices that impede the flow of such information. Pub. L. No. 114-255, 130 Stat. 1033, 1176-1180 (2016). But Congress recognized that actors should not be expected to provide unlimited access to health information to any requester, in whatever manner requested. The Cures Act thus instructs HHS to identify “reasonable and necessary” exceptions to the general ban. 42 U.S.C. § 300jj-52(a)(3).

One such exception is the “Manner Exception,” which HHS designed to give actors control over the “manner” in which they respond

to requests for electronic health information. Under the Exception, an actor's choice to "limit[] the manner in which it fulfills a request" for information "will not be considered information blocking" if it satisfies either of two criteria. 45 C.F.R. § 171.301. First, the actor may provide the information in the manner requested, under whatever market-based contractual arrangement to which the parties agree. *Id.* § 171.301(a)(2). Second, if the actor "cannot reach agreeable terms" (or is "technically unable" to fulfill the request), it may provide the information using one of the standards-based solutions or other transmittal methods designated by HHS. *Id.* § 171.301(b)(1).³ In this way, the Manner Exception expressly permits *either* market solutions or standards-based solutions designated by HHS.

B. Imposing A Duty To Negotiate Is Inconsistent With The Cures Act And Flouts HHS's Regulations

The panel, however, read into the phrase "cannot reach agreeable terms" an open-ended duty to negotiate. Specifically, the panel held that the phrase "'cannot reach agreeable terms' *** must imply at least some

³ Industry-developed standards best enable communication between different systems, regardless of the technology or provider. That is why mobile phone companies use standardized messaging protocols: they ensure a Verizon iPhone can send messages to a T-Mobile Android.

reasonable efforts and articulable reasons why the parties *cannot* come to an agreement.” Op. 43. It further held that an actor “must show some good-faith efforts to reach agreeable terms before claiming that it ‘cannot’ do so.” *Id.* at 42 n.12.

Those requirements are pure judicial inventions. Nothing in the Cures Act states (or implies) that actors should be forced to negotiate customized, non-standard requests for electronic health information, even if the actors are “technically” able to fulfill such requests through new technology solutions. Unlike other parts of the broader statutory scheme governing health information technology and exchange, *see, e.g.*, 42 U.S.C. §§ 300jj-11, 300jj-14, the information-blocking prohibition neither imposes, nor authorizes HHS to impose, new technological requirements for otherwise compliant health IT systems.

Nor does the Manner Exception impose any affirmative, compulsory duty to negotiate. By contrast, other HHS information-blocking exceptions (which are voluntary) *do* require actors to negotiate to benefit. *See, e.g.*, 45 C.F.R. § 171.303(a) (to satisfy “[l]icensing exception,” actor must “[b]egin license negotiations” with “requestor within 10 business days from the receipt of the request”); *cf. Jama v. ICE*,

543 U.S. 335, 341 (2005) (when Congress includes language in one section but omits it elsewhere, that choice is presumed intentional).

A duty to negotiate is also fundamentally inconsistent with the preamble to the rule adopting the Manner Exception, which makes clear that actors who simply “do not want” to fulfill a request in the manner requested need not do so, so long as they offer at least two standardized alternatives. *See, e.g., 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*, 85 Fed. Reg. 25,642, 25,807 (May 1, 2020) (“[U]nder the [Manner Exception] *** actors *who do not want to* license their interoperability elements will not be required to do so if they are able to respond in an alternative manner[.]”) (emphasis added); *id.* at 25,892 (Manner Exception allows “actors *who do not want to* license their [intellectual property (‘IP’)] to respond in an alternative manner that does not require the licensing of proprietary IP”) (emphasis added); *see also id.* at 25,868, 25,878, 25,893 (similar). Although an actor is always “allow[ed]” to attempt to negotiate

agreements to supply information as requested, *id.* at 25,877, the preamble shows that negotiation is never “required,” *id.* at 25,807.⁴

In fact, imposing such a duty would frustrate the carefully crafted regulatory scheme. HHS recognized that promoting interoperability and a standards-based exchange of electronic health information is a vital purpose of the information-blocking regulations. *See* Rehearing Pet. 9. Yet the panel’s rule removes the incentive for requestors to seek out standards-based solutions. And it will likely chill development of standards-based technologies as actors understandably focus their resources on “reasonable” and “good faith” negotiations over bespoke development tools to avoid information-blocking liability.⁵

⁴ *Amici* agree with PointClickCare that the panel erred by suggesting (in dicta) that offering “USCDI” data is an inadequate alternative. *See* Rehearing Pet. at 10-13. USCDI is a recognized “content and transport standard,” and actors need not offer an unlimited number of alternatives. *See, e.g., Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*, 89 Fed. Reg. 1,192, 1,382-1,383 (Jan. 9, 2024).

⁵ Requiring actors to negotiate non-standard terms will inevitably lead to different terms for different requestors, contrary to other information-blocking exceptions that require actors to be consistent and non-discriminatory. *See* 45 C.F.R. § 171.302(a); *id.* § 171.303(b)(3).

II. THE PANEL'S NEGOTIATION REQUIREMENT WILL HAVE SERIOUS ADVERSE CONSEQUENCES

A. Requiring Actors To Negotiate Every Request They Receive Will Create A Logistical Nightmare

The panel's negotiation requirement will have immediate, deleterious consequences. Providers and EHR vendors receive countless requests for electronic health information each year—which may involve requests for non-standard access or exchange—from a variety of requestors. Actors cannot realistically engage in customized “reasonable” and “good faith” negotiations for every request, let alone separately administer distinct contractual terms for all of them. For hospitals in particular, negotiating methods of information exchange can be a major distraction from their core mission of providing care. *See AHA, Regulatory Overload* 24 (Oct. 2017) (describing how providers must “quickly mobilize staff” to respond to “new or updated regulat[ory]” requirements).⁶

Some requests may be so unreasonable or impractical that there are no “terms” to which the actor would agree—rendering any negotiation a wasted exercise. Say, for example, a third-party asks an EHR developer

⁶ <https://www.aha.org/sites/default/files/regulatory-overload-report.pdf>.

to create a complex and non-standard technology to integrate with the developer's software, requiring hundreds or thousands of hours of development and testing. Or a patient asks a hospital to provide health records in an outdated format, like a floppy disk, that the hospital's technology no longer supports. Even if an actor were "technically []able" to fulfill such a request, the time and expense involved would be commercially infeasible.

Yet, under the panel's decision, the actor would still have to make a "good faith" effort to negotiate the "terms" of those requests to protect itself against a later allegation that its actions were insufficiently "reasonable." Not only that, but the actor would need to extensively document its efforts to negotiate in anticipation of litigation, given that, under the panel's decision, the developer or hospital bears the burden of offering "articulable reasons" for the negotiations' failure. *See* Op. 38-39; Rehearing Pet. 18-20. Because HHS already permits standards-based solutions as alternative manners, all these efforts will be a pointless waste of time and resources.

B. Requiring Actors To Negotiate Every Request They Receive Will Invite Wasteful Litigation

To make matters worse, the panel's negotiation requirement will lead to weaponization of requests for non-standard connections and breed litigation. As this case demonstrates, a supposed failure to engage in "good faith" negotiations is now apparently actionable as a state-law unfair competition claim in Maryland (and beyond, if other circuits follow this erroneous decision). As a result, third parties—even direct competitors—can lodge requests for information and new interoperability technology in whatever manner they want, and if the actor does not negotiate to their liking, those third parties can easily cry foul and litigate. They will never have to prove that their request was reasonable or practicable, or that the actor was operating in bad faith. Instead, the burden is now on the *actor* to prove otherwise. Op. 43; see Rehearing Pet 18-20.

Those private state-law suits will, in turn, lead to inconsistent and contradictory information-blocking policy. See Am. Br. 20 (quoting Stephen B. Burbank et al., *Private Enforcement of Statutory and Administrative Law in the United States (and Other Common Law*

Countries) 42 (All Faculty Scholarship, Paper No. 357, 2014).⁷ As even the panel acknowledged, the resulting lack of “predictability” creates “genuine concerns *** for regulated entities.” Op. 35.

C. Requiring Actors To Negotiate Every Request They Receive Will Impose More Costs On Our Nation’s Healthcare System

Finally, negotiating each and every request will divert money away from patient care, economically devastate vulnerable healthcare providers, and raise costs for actors nationwide. Inevitable litigation will also dramatically raise compliance costs. *See* Am. Br. 23. And those costs will ultimately be borne by the healthcare system, including healthcare providers and their patients. *See* AHA, *Regulatory Overload*, *supra* p. 10, at 34 (finding that Medicare rules requiring electronic information exchange led to significant administrative and financial burdens on healthcare systems due to “manual workarounds” necessitated by other providers’ lack of technological capability).

Unless an actor can demonstrate a request is “technically unable” to be fulfilled—no matter how unreasonable—developers and hospitals

⁷ https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1346&context=faculty_scholarship.

must be prepared to invest resources in negotiating solutions. When parties agree on such nonstandard solutions, they must be maintained and tested with every update to EHR software and will not be scalable—meaning actors will spend time and money on a one-time deal. The potential proliferation of non-standard integrations will ultimately undermine HHS’s goal of interoperability.

Even requesting a standard solution under nonstandard terms could increase costs. As a practical matter, to comply with both the information-blocking prohibition and requirements under HHS’s Health IT Certification Program, 45 C.F.R. § 170.404(a)(2)(ii), and to help requestors determine the best technological solutions for their needs, certified EHR vendors publish their standard terms for their standards-based technologies. Deviation from these standard terms through obligatory negotiations introduces risk and costs for these actors. *See* note 5, *supra*.

Moreover, certified EHR systems used in thousands of hospitals nationwide already meet extensive federal criteria under HHS’s Health IT Certification Program, including criteria designed for the standards-based exchange of patient information. 42 C.F.R. §§ 414.1305, 414.1375;

45 C.F.R. part 170. Certification is costly, and those costs are ultimately borne by our healthcare system. *See* 85 Fed. Reg. at 25,918 (estimating that implementing a *single* new standard transmission technology would require up to 6,000 hours); *id.* at 25,922 (estimating that implementing software applications that engage with certain transmission technologies could cost providers up to \$929.3 million). The panel’s decision requires actors to negotiate in “good faith” over whether to add countless new functionalities to their systems on demand, and then to either reach agreement or defend their conduct when negotiations fail—further increasing costs that our healthcare system must ultimately bear.

CONCLUSION

The Court should grant the petition for rehearing.

Dated: April 2, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(b)(4) because it contains 2,599 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it was prepared in a proportionally spaced typeface using Microsoft 365, 14-point Century Schoolbook font.

/s/ James E. Tysse
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April 2, 2025